

Remarks

By this amendment, claims 1, 2, 4, and 5 are amended, and claims 9-13 are canceled. Claims 1-8 are pending and under consideration.

The foregoing amendments are made to insert the required SEQ ID NO identifiers associated with various listed sequences. The amendments are also made to even more clearly define the claimed invention and do not add new matter. Support for the amendments can be found throughout the specification and claims as filed, e.g., page 8, line 18 – page 9, line 3; and page 9, line 27 – page 10, line 8. Reconsideration of the rejected claims in view of the above amendments and the following remarks is respectfully requested.

Amendments

Applicants thank the Examiner for acknowledgment of the papers filed January 4, 2008, and for consideration of the same.

Specification

The Office Action objects to the disclosure because Figures 14 and 17 contain nucleic acid sequences without corresponding reference to SEQ ID NOs within the Figure or in the Figure Legend.

Applicants submit that the instant amendment is responsive to the objection, and respectfully request withdrawal of the same.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Office Action rejects claims 1-8 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Office Action states that the claims are construed to include “an isolated regulatory element that is capable of enhancing gene expression efficiency in a motor or sensory neuron, wherein the structural characteristics of the claimed regulatory element are essentially unlimited” (see Office Action dated April 3, 2008 at page 4, lines 11-13). In particular, the Office Action states that “[c]laims 1, 2, 4 and 5 are broad and read on any sequence capable of eliciting the same enhancing capabilities of the SEQ IDs listed in the claims by deletion, substitution or addition of one to thirty nucleotides” (Office Action dated April 3, 2008 at page 4, lines 32-34).

Furthermore, in response to the Remarks submitted on September 24, 2007, the Office Action asserts that “the limitation of ‘up to 30 deletions, substitutions or additions’ is indefinite because there is no disclosure if these deletions, substitutions or additions are to a single nucleotide, or a region of the original sequence.” (Office Action dated April 3, 2008 at page 6, lines 16-19). The Office Action also asserts that “[a] single deletion could encompass 98% of the original sequence, which reads on more than 5% of the bases in the original sequences, yet could ablate enhancer function” (Office Action dated April 3, 2008 at page 6, lines 19-20).

In response, and without acquiescing to the propriety of the assertions set forth in the rejection of the claims under 35 U.S.C. § 112, first paragraph, Applicants submit that instant amendment is responsive to the rejection. In particular, Applicants submit that the claimed subject matter is drawn to, e.g., “[a]n enhancer consisting of the following DNA (a) or (b):

(a) DNA consisting of the nucleotide sequence as shown in any one of SEQ ID NOs: 1 to 4; or

(b) the DNA according to part (a), above, in which one to thirty **nucleotides** have been

deleted, substituted, or added, and which is capable of enhancing gene expression efficiency in motor neurons” (emphasis added). Applicants submit that the Office’s interpretation of the claims is inconsistent with the specification. Applicant’s further submit that the claimed subject matter encompasses nucleic acid sequences which are at least 95% homologous and which have a particular function, i.e. capable of enhancing gene expression efficiency in motor or sensory neurons. Applicants further submit that the subject matter of claim 2 encompasses sequences with at least 96% or 97% homology to the recited portions of SEQ ID NOs: 1-4.

Applicants further submit that the specification clearly describes the common features or areas of homology between SEQ IDs 1-6 and their common function (see, e.g., page 10, lines 2-20, in the specification). In particular, the specification indicates that

[t]he region between nucleotides 235 and 560 of SEQ ID NO: 1, the region between nucleotides 204 and 528 of SEQ ID NO: 2, the region between nucleotides 206 and 530 of SEQ ID NO: 3, and the region between nucleotides 211 and 555 of SEQ ID NO: 4 are highly homologous to one another and are highly conserved among species. Accordingly, it is suggested that these regions of SEQ ID NOs: 1 to 4 **contribute to functions of enhancers for improving gene expression efficiency in motor neurons**. The region between nucleotides 378 and 553 of SEQ ID NO: 5 and the region between nucleotides 178 and 353 of SEQ ID NO: 6 are highly homologous to each other and are highly conserved among species. Accordingly, it is suggested that these regions of SEQ ID NOs: 5 and 6 **contribute to functions of enhancers for improving gene expression efficiency** in sensory neurons and/or in motor neurons that extend axons ventrally

(page 10, lines 9-20; emphasis added). Thus, the specification clearly describes that these areas of homology function as “enhancers for improving gene expression efficiency in motor neurons,” thereby establishing a common feature with an associated common function among these sequences.

Accordingly, Applicants submit that the specification describe the common *function* of the claimed genus of sequences. Furthermore, the specification describes the common *structure*

of the claimed genus of sequences by describing the regions of homology in SEQ ID NOs. 1-6, and the location of these homologous regions within SEQ ID NOs. 1-6 (*see, e.g.*, page 10, paragraph 1).

Therefore, one skilled in the art would appreciate the common structural features of the claimed genus of sequences, and would be convinced that the Applicants were indeed in possession of the claimed invention at the time of filing. Accordingly, Applicants submit that that the specification sufficiently describes the common structural features that the specification sufficiently defines the function recited in the claims, thereby clearly defining the claimed genus of sequences.

Accordingly, Applicants respectfully request that the rejection be withdrawn.


Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of all outstanding rejections, and an indication of the allowability of all claims pending in the present application in due course.

No additional fee is believed due at this time. However, should any fee be required, the Office is authorized to charge the same to Deposit Account No. 19-0089.

Should the Examiner have any questions or comments regarding this response, or the present application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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